

## **PROGRAM 6 MONTH INJECTABLE FOR CATS - lufenuron injection, suspension**

Novartis Animal Health US, Inc.

### **6 Month Injectable for Cats**

The six-month injection that controls flea populations in cats.

### **CAUTION**

U.S. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

### **DESCRIPTION**

PROGRAM® (lufenuron) 6 Month Injectable for Cats is available in two syringe sizes for subcutaneous administration to cats and kittens according to their weight (See Dosage). Each preloaded syringe is formulated to provide 4.54 mg/pound (10 mg/kg) body weight of lufenuron. The active ingredient of PROGRAM 6 Month Injectable for Cats is lufenuron, a benzoylphenyl-urea derivative with the following chemical composition: N-[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoropropoxy)-phenylaminocarbonyl]-2,6-difluorobenzamide. Benzoylphenyl-urea compounds, including lufenuron, are classified as insect development inhibitors (IDIs).

### **MODE OF ACTION**

Lufenuron, the active ingredient of PROGRAM 6 Month Injectable for Cats, is an insect development inhibitor which breaks the flea life cycle by inhibiting egg development. Lufenuron's mode of action is interference with chitin synthesis, polymerization and deposition. Lufenuron has no effect on adult fleas.

After biting a lufenuron-treated cat, the female flea ingests a blood meal containing lufenuron which is subsequently deposited in her eggs. Lufenuron prevents flea eggs from hatching and developing into adults and thus controls flea populations by breaking the life cycle. (See Efficacy.)

### **INDICATIONS**

PROGRAM 6 Month Injectable for Cats is indicated for use in cats, six weeks of age and older, for the control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

### **WARNING**

**Do not use in dogs. A severe local reaction may occur in dogs that is not seen in cats.**

### **PRECAUTIONS**

The safety of PROGRAM 6 Month Injectable for Cats in reproducing animals has not been established.

PROGRAM 6 Month Injectable for Cats breaks the flea life cycle by inhibiting egg development. However, pre-existing flea populations may continue to develop and emerge after treatment with PROGRAM 6 Month Injectable for Cats. Based on results of clinical studies, this emergence generally occurs during the first 30-60 days. Therefore, noticeable control may not be observed until several weeks after dosing when a pre-existing infestation is present. Cooler geographic areas may have longer lag periods due to a prolonged flea life cycle. Insecticides may be used concurrently depending on the severity of the infestation.

### **EFFICACY**

Laboratory and clinical trials have shown that PROGRAM 6 Month Injectable for Cats is a safe, effective and convenient method to control flea populations. A single dose provides long-lasting control for a full 6 months.

In laboratory studies, PROGRAM 6 Month Injectable for Cats provided a cumulative percent control of egg development of 94.8% and 97.7% beginning 14 days post-treatment through six months post-treatment in the dose titration and dose confirmation studies, respectively. There was a 2-3 week "induction phase" in these studies before significant effects on flea reproduction were seen. PROGRAM 6 Month Injectable for Cats was effective in controlling flea populations when administered to 183 pet cats in a clinical setting. At study initiation, treated cats averaged 43 fleas per cat. Six months post-injection these cats averaged 11 fleas per cat.

### **SAFETY**

PROGRAM 6 Month Injectable for Cats has been used and tested safely in over sixteen breeds of cats, including females, males and kittens. In well-controlled clinical trials, 294 cats were treated with lufenuron. PROGRAM 6 Month Injectable for Cats has also been safely used in cats receiving frequently used veterinary products such as vaccines, anthelmintics, antibiotics, steroids and insecticides. The acute toxicity of injectable lufenuron was evaluated by administering 100 mg/kg bw, 10x the recommended 10 mg/kg bw dose rate, to adult cats. The potential cumulative toxicity of 1x and 3x the 10 mg/kg six month use rate of lufenuron injectable in 2 week old kittens was evaluated over a two month period. Other than injection site reactions (see below), no clinical signs of toxicity were reported in these studies.

Cumulative toxicity of injectable lufenuron in 2 month old cats was evaluated by administering 1, 3, or 5x the six-month dose three times during the 6 month study. This equates to cumulative doses of 3X, 9X, and 15X, respectively. Other than injection site reactions (see below), no clinical signs of toxicity were reported in these studies. Heinz body inclusions were present in all the control and

treated cats, however, erythrocytes in the 50 mg/kg (15x cumulative dose) group had slightly elevated levels of Heinz bodies at 3-6 months.

The following injection site reactions were noted in these laboratory studies. Transient, minor discomfort was noted in some kittens and cats upon injection. Small raised areas at the injection sites, presumed to be deposits of lufenuron, were seen immediately after administration and persisted in some cases for the duration of the studies. This response at the injection site correlated microscopically with acute to granulomatous inflammation and fibrosis. Older injection sites showed less inflammation which indicates these effects may resolve with time. No neoplastic transformations were found. (See Adverse Reactions.)

## DOSAGE

PROGRAM 6 Month Injectable for Cats is injected subcutaneously once every six months at the recommended minimum dosage of 4.54 mg lufenuron per pound (10 mg/kg) of body weight.

## RECOMMENDED DOSAGE SCHEDULE

Body Weight	Syringe Size	Lufenuron Dose
Up to 8.8 lbs. (4.0 kg)	Small (0.4 ml)	40 mg
8.9 lbs. to 17.6 lbs. (4.1 to 8.0 kg)	Large (0.8 ml)	80 mg

## ADMINISTRATION

Administer PROGRAM 6 Month Injectable for Cats subcutaneously using standard injection technique. Before administration, shake well to thoroughly mix the sterile suspension. Remove the needle guard and subcutaneously inject the entire contents of the syringe.

**Do not inject intramuscularly.** The empty syringe should be disposed of in an approved manner.

To ensure the greatest benefits from the use of PROGRAM 6 Month Injectable for Cats, it is important to treat all cats within a household. All dogs within the household should be treated with lufenuron tablets. Untreated dogs and cats may develop infestations which could reduce the overall flea control within a household.

**Do not administer this product to dogs.**

## ADVERSE REACTIONS

The following adverse reactions were observed in clinical field trials with PROGRAM 6 Month Injectable for Cats: pain on injection, injection site lumps/granulomas, vomiting, listlessness/lethargy and anorexia.

Histologic examination of one cat's injection site lump showed evidence of inflammation surrounding an area of necrosis with marked proliferation of fibrous connective tissue. In another cat, granulomatous inflammation was noted which included non-pleomorphic fibrocytes and fibroplasia.

## HOW SUPPLIED

PROGRAM 6 Month Injectable for Cats is available in 0.4 ml and 0.8 ml unit dose syringes, formulated according to the weight of the cat. Unit dose packs are available in packages of 10 syringes per carton.

## STORAGE CONDITIONS

PROGRAM 6 Month Injectable for Cats should be stored at room temperature between 59° and 86 °F (15-30 °C).

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Manufactured for:

Novartis Animal Health US, Inc.,

Greensboro, NC 27404

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## PRINCIPAL DISPLAY PANEL

**Package Label – 40 mg**

FOR CAT

TREATMENT ONLY

NOVARTIS

PROGRAM® (LUFENURON) 6 MONTH INJECTABLE FOR CATS

40 mg.

up to 8.8 lbs.

Net Contents: Each syringe contains

40 mg LUFENURON in 0.4 mL

**Contents: 10 syringes**

Product #50911

NADA# 141-105, Approved by FDA

**Caution:** Federal (USA) law restricts this drug to be used by the order of a licensed veterinarian.

**Keep this and all drugs out of the reach of children**



## PRINCIPAL DISPLAY PANEL

**Package Label – 80 mg**

**FOR CAT**

**TREATMENT ONLY**

**NOVARTIS**

**PROGRAM® (LUFENURON) 6 MONTH INJECTABLE FOR CATS**

**80 mg.**

**8.9 to 17.6 lbs.**

**Net Contents: Each syringe contains**

**80 mg LUFENURON in 0.8 mL**

**Contents: 10 syringes**

**Product #50921**

**NADA# 141-105, Approved by FDA**

**Caution:** Federal (USA) law restricts this drug to be used by the order of a licensed veterinarian.

**Keep this and all drugs out of the reach of children**

